UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,126	01/12/2001	Kazuhiro Tsujita	Q61243	8903

7590 07/13/2007

SUGHRUE, MION, ZINN, MACPEAK & SEAS, PLLC
2100 Pennsylvania Avenue, N.W.,
Washington, DC 20037-3202

EXAMINER	
ROZANSKI, MICHAEL T	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
07/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/758,126	TSUJITA ET AL.	
	Examiner	Art Unit	
	Michael Rozanski	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15 and 33-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15 and 33-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 6/26/07 have been fully considered but they are not persuasive. With regard to the claim objections, Examiner upholds the assertion that the claims merely recite the natural response of tissue to excitation light, and thus not further limiting. It is the natural response of living body tissues exposed to excitation light to have greater fluorescence than the reflected reference light. Similarly, the 35 U.S.C 101 rejection is upheld. Excitation light induces tissue to fluoresce over a spectrum of wavelengths, wherein the intensity at which the excited tissue fluoresces is increased (see col. 1, lines 20-40 of US Patent 5,467,767) and, thus, greater than reflected reference light. With regard to the rejected claims, the rejection is upheld because while Richards-Kortum discloses higher and lower intensities for adenomas, the Applicant's claims higher intensity is taught nonetheless. Therefore, the previous office action rejection is upheld, repeated below, and made FINAL.

Response to Amendment

2. The amendment filed 6/26/07 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Newly added claims 48-57 are drawn to abnormal area having a higher intensity through the entire wavelength

region, throughout part of the wavelength region, for wavelengths greater than 480 nm, for wavelengths below 430 nm, or for wavelengths above 640 nm. These limitations are not supported by the specification.

Applicant is required to cancel the new matter in the reply to this Office Action.

Even in the event that these claims were supported in the specificaiton, Richards-Kortum teach of fluorescence intensity greater in adenomas for 400-420 nm (which is below 430 nm) and greater in normal tissue for 430-480 nm (col. 13, lines 6-11). Above 680 nm (which is greater than 480 nm and 640 nm), intensity of adenoma is also greater than normal tissue (col. 13, lines 12-14). While the abnormal wavelength region is not greater throughout the entire wavelength region, it would have been obvious to one with ordinary skill in the art at the time the invention was made to have incorporated teachings where the abnormal intensity is greater through part of the wavelength region as greater abnormal intensity over the entire wavelength would permit distinction over any wavelength. This would allow to better distinction to be made, such as at the greatest difference in abnormal/normal intensity.

Claim Objections

3. Claims 39-43 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. The claims merely recite the response of the tissue to excitation light, which is a natural process rather than how the invention utilizes that response to provide a useful result. As such these responses do not further limit.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 39-43 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims recite the natural response of a tissue to excitation light. As such they do not fall under the statutory categories of invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-15 and 33-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palcic et al. '190 (US 5,827,190) in view of Richards-Kortum et al (US 5,421,337).

Palcic et al. teach normalization of at least one fluorescence image by using a remittance image or as otherwise stated, reflected reference light image, in order to correct for many factors including light intensity allowing for differentiation of normal and diseased tissue (col. 2, line 20-col. 3, line 37). Palcic et al. teaches the use of a

remittance image to account for non-uniformity due to different changes including illumination intensity (col. 2, lines 28-31).

While Palcic et al. do not specifically address specified values, it would have been obvious to one skilled in the art at the time that the invention was made that the normalization process necessarily incorporates specified values or thresholds in order to differentiate normal from abnormal tissue as this is well within the knowledge of skilled artisans.

With respect to claims 33-43, necessarily the detected values of fluorescence will be above or below the remittance value depending on whether the tissue is normal or abnormal.

In addition, Palcic et al. do not teach that diseased tissue will have a higher intensity, and that normal tissue will have a lower intensity (as described in col. 6, lines 44-51). In the same field of endeavor, Richards-Kortum et al. teach of adenomatous tissue with higher intensity and normal tissue with lower intensity, both with reference to a specified wavelength value (col. 11, lines 3-10; col. 12, line 64-col. 13, line 15). It would have been obvious to one with ordinary skill in the art at the time the invention was made to improve the diagnosis of tissues regarding the condition of tissue.

With respect to claim 33 and claims 44-47, Palcic et al. also do not specifically mention chrominance or luminance signal components with respect to the fluorescence image and reflected reference light or judgment means based on a ratio. However, Richards-Kortum et al. make reference to correlation features of fluorescence spectra to

tissue type in a quantitative way using ratios of fluorescence intensities at various wavelengths from the fluorescent image and reflected reference light (col. 9, lines 10-34). In addition, color (chrominance) and intensity (luminance) components of autofluorescence are recorded for analysis (col. 21, lines 15-55). It would have been obvious to one with ordinary skill in the art at the time the invention was made to improve the diagnosis of tissues by through a better display of fluorescence images.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Rozanski whose telephone number is 571-272-1648. The examiner can normally be reached on Monday - Friday, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571-272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MR

ELENI MANTIS MERCADER
SUPERVISORY PATENT EXAMINER